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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pulmonary-Allergy Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pulmonary-Allergy Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on November 22, 1999, 8 a.m. to 5 p.m. and November 23, 1999, 7:45 a.m. to 4 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8210 Wisconsin Ave., Bethesda, MD.

Contact Person: Leander B. Madoo, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, or FDA Advisory Committee Information Line, l-800-741-8138 (301–443–0572 in the Washington, DC area), code 12545. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 22, 1999, FDA will discuss its regulations related to ozone-depleting substances. In this discussion, FDA will review the Montreal Protocol on substances that deplete the ozone layer and the advanced notice of proposed rulemaking published on March 6, 1997 (62 FR 10242), as discussed at the April 11, 1997, committee meeting. FDA will provide an overview and detailed discussion of the proposed rule published on September 1, 1999 (64 FR 47719), related to the phase-out of chlorofluorocarbons (CFC's) in metered-dose inhalers. The proposed rule outlines the mechanism by which FDA will determine when the use of ozone-

depleting substances, including CFC's in metered-dose, inhalers, in any product regulated by FDA is no longer essential under the Clear Air Act. The proposed rule can be downloaded at http://www.fda.gov/ohrma/dockets/98fr/090199b.pdf. FDA has also created a website at http://www.fda.gov/cder/mdi to provide information to the public regarding this proposal and the issues related to CFC use in medical products. The committee will discuss and comment on the proposed rule and on the presentations made during the public hearing.

On November 23, 1999, the committee will discuss the safety and efficacy of new drug application (NDA) 21-077 for three products: (1) Advair™ Diskus® 100 micrograms (µg) (salmeterol xinafoate 50 µg/fluticasone propionate 100 µg inhalation powder), (2) Advair™ Diskus® 250 µg (salmeterol xinafoate 50 µg/fluticasone inhalation powder), and (3) Advair™ Diskus® 500 µg (salmeterol xinafoate 50 µg/fluticasone propionate 500 µg inhalation powder), Glaxo Wellcome, for the maintenance treatment of asthma as prophylatic therapy in patients 12 years of age and older.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 12, 1999. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 12:30 p.m. on November 22, 1999, and between approximately 8 a.m. and 8:30 a.m. on November 23, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 12, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 22, 1999

Linda A. Suydam
Senior Associate Commissioner

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